

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 21, 2003, from 8:30 a.m. to 4:30 p.m., and October 22, 2003, from 8:30 a.m. to 5 p.m.

Location: Best Western Washington Gateway Hotel, 1251 West Montgomery Ave., Rockville, MD.

Contact Person: Hilda Scharen, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 21, 2003, the committee will do the following: (1) Receive updates from the Manufacturing, Clinical Pharmacology, and Pharmacology/Toxicology Subcommittees, (2) discuss and provide comments

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on the FDA draft guidance for industry entitled “Process Analytical Technologies (PAT), a Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance,” (see the FDA Internet Web address <http://www.fda.gov/cder/guidance/5815dft.htm>), and (3) discuss and provide comments on parametric tolerance interval test for dose content uniformity. On October 22, 2003, the committee will do the following: (1) Discuss and provide comments on risk based Chemistry Manufacturing and Control (CMC) review proposals, (2) discuss and provide comments on nomenclature, and (3) discuss and provide direction to the research plan for generics.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by October 10, 2003. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on October 21, 2003, and between approximately 1 p.m. and 2 p.m. on October 22, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 10, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

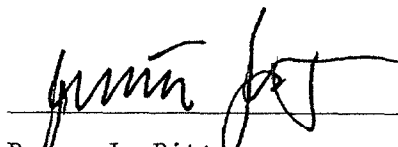
Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a

disability, please contact Hilda Scharen at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 9/25/03
September 25, 2003.



Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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